IN THE DRAWINGS

The attached sheet of annotated drawings includes changes to Fig. 3. This sheet, which includes Fig. 3, replaces the original sheet including Fig. 3.

Attachment: Annotated Sheet

REMARKS

Claims 34-53 are pending. The specification has been revised to correct some evident typographical and editorial errors. Support for the changes on pages 36 and 40 is found in the original sequence listing. A correction has been made to Fig. 3 and an annotated figure is provided for approval by the Examiner. Basis for this correction is evident from the specification which discloses Tables 2 and 3, but not Tables 4 and 5.

New Claims 34-53 find support in the original claims and track the Examiner suggestions. Independent Claim 34 is limited to HCV sequences as shown in SEQ ID NOS: 1-15 as first probe sequences. Second probe sequences are directed to SEQ ID NOS: 37-40. Accordingly, no new matter has been introduced.

The Applicants thank Examiner Switzer for the courteous and helpful interview of June 29, 2006. The potential rejoinder of non-elected species of HCV probes was discussed and the Examiner indicated that rejoinder was more likely if the allowability of the claims depended on the sequences of the MxA probes (the second probe). Editorial corrections to the specification were discussed and it was agreed that the sequence listing provides descriptive support for a variable position at 420 in SEQ ID NOS: 37-40. It was suggested that the Applicants adopt the language proposed in the prior Official Action (see page 18) to avoid indefiniteness issues. It was indicated that the double patenting rejections could be overcome by filing a terminal disclaimer.

Restriction-Election

The Applicants previously elected Group II, and SEQ ID NO: 1 and a probe having bases 415-425 of SEQ ID NO: 38. This Requirement has now been made FINAL. The Applicants thank Examiner Switzer for rejoining the species of second probe corresponding

to SEQ ID NOS: 37-40 and for agreeing to consider rejoinder of other species of the first probe (i.e., as directed to HCV sequences).

Objection—Specification and Claims

The specification and claim 23 were objected to for various informalities. These objections are moot in view of the amendments above.

Rejection—35 U.S.C. §112, second paragraph

Claims 19, 23, 24 and 25 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. These rejections are moot in view of the cancellation of these claims.

Rejection—35 U.S.C. §102

Claims 18, 19, 22, 24, 32 and 33 were rejected under 35 U.S.C. 102(b) as being anticipated by Maertens et al., U.S. Patent No. 5,864,704. These rejections are moot in view of the cancellation of these claims and would not apply to the new claims which require the presence of first probes which comprise particular HCV sequences and second probes which comprise particular MBL polymorphism sequences. Maertens does not disclose the specific MBL polymorphism sequences.

Furthermore, the Official Action indicates that Maertens et al. disclose the first probe and the second probe of the present invention. However, the probes of Maertens et al. are only disclosed as probes for detecting I-ICy. Therefore, the probes of Maertens et al. are clearly different from the unique idea of the present invention recited in amended claim 18, that is, an apparatus for obtaining information concerning gene of an individual and information concerning a pathogenic microorganism existing in the individual, from the same one specimen from the individual.

In the technical field of the present invention, if two different genetic information items are to be obtained from an individual, generally the information items are detected by preparing separate specimens for the respective information items. For example, in the case of using blood, nucleic acid information of an individual subject is obtained by preparing a nucleic acid from a blood cell in the blood, and obtaining a sequence of the nucleic acid. On the other hand, information of a nucleic acid derived from a pathogenic microorganism is generally obtained by preparing a nucleic acid from serum, not a blood cell, in the blood of the individual subject and obtaining a sequence of the nucleic acid. Therefore, in the case of preparing both the above nucleic acids, it is necessary to separate serum and blood cells in the blood, preparing separate nucleic acid samples from respective fractions, and obtaining the sequences of the nucleic acids. This is performed mainly to enhance the refining degree of the nucleic acid samples and enhance the accuracy of sequencing. Therefore, in this technical field, generally a nucleic acid derived from serum and a nucleic acid derived from blood cell are separately detected, if sequence information items are to be obtained from nucleic acids derived from individual subject and a pathogenic microorganism by using, for example, blood.

Therefore, the idea of detecting two different sequence information items simultaneously from the same specimen as in the present invention is an entirely original idea, and contrary to the common knowledge of the technical field. As a matter of course, there are no apparatuses for obtaining a plurality of genetic information items from one specimen, and such apparatuses have never been developed before the present invention.

Further, in the conventional test, the object of the test is achieved by performing only one of, for example, obtaining genetic information from blood cell and obtaining genetic information from serum, according to the number of information items to be obtained. Performing one of them is a common technical knowledge of one skilled in the art, and

performing two tests simultaneously is contrary to the common technical knowledge of one skilled in the art as complicating the detection process.

In comparison with this, the inventors of the present invention have found that relationship between genetic information of human and genetic information of a virus has a strong correlation with the efficacy of treatment for the disease caused by the virus. The finding of the correlation has enabled the inventors to achieve the present invention. As described above, although performing two tests simultaneously and complicating the detection process is contrary to the common technical knowledge of one skilled in the art, the inventors of the present invention have proposed an apparatus which simultaneously performs tests of both the human genetic information and the viral genetic information. This apparatus first enables estimate of treatment for the disease.

An important aspect of the apparatus of the present invention is the unique idea of simultaneously detecting nucleic acids of an individual from the same specimen, that is, a nucleic acid of a pathogenic microorganism and a nucleic acid of said individual associated with responsiveness to a treatment for the disease. Further, the idea produces the effect of first enabling estimate of treatment for the disease.

As an example, the Example of the present application clearly recites that SNP relating to MxA and MBL of an individual subject and a type of HCV are simultaneously detected. Using these information items together synergistically enhances the detection accuracy of the efficacy of IFN (refer to Tables 2 and 3 and page 62 of the English text). Maertens et al. neither discloses nor suggests the above remarkable effect of the present invention. Further, the above effect is not regarded as being clear from the technical standard when the present application was filed. It has been first found by the inventors of the present invention that there is correlation, which determines the efficacy of IFN treatment, between sequence of the genes of human of MxA and MBL and sequence of HCV gene determining

the type (such as type 1 and type 2) of HCV. The present invention has been first achieved on the basis of the above finding. However, please note that the idea of the present invention does not only relate to MxA, MBL and HCV. The idea itself of simultaneously detecting nucleic acids of an individual from the same specimen, that is, a nucleic acid of a pathogenic microorganism and a nucleic acid of said individual associated with responsiveness to a treatment for the disease is unique and produces a remarkable effect. The idea is first provided by the present invention.

Rejection—35 U.S.C. §103

Claims 18, 19, 20, 22, 23, 24, 25, 32 and 33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Maertens et al., U.S. Patent No. 5,864,704, in view of Hijikata et al., Intervirology, 2000. This rejection is moot in view of the cancellation of these claims and would not apply to the present claims for the following reasons.

As discussed above, Maertens does not disclose the required MBL polymorphism sequences nor provide any suggestion for combination of an HCV sequence of SEQ ID NO: 1-15 with an MBL polymorphism sequence of SEQ ID NO: 37-40.

Hijikata et al. was cited as disclosing a correlation between a polymorphism in the MxA gene promoter and patient response to HCV therapy (see abstract). However, this polymorphism is at a different position than the polymorphisms encompassed by bases 415-425 of SEQ ID NOS: 37-40 as shown below:

SEQ ID NO: 37 gctg**t**aggtg

SEQ ID NO: 38 gctg**g**aggtg

SEQ ID NO: 39 gctg**a**aggtg

SEQ ID NO: 40 gctg**c**aggtg

The G/T polymorphism described in Fig. 1 of Hijikata is at position -88 and is within a different base sequence (the polymorphism of SEQ ID NOS: 37-40 is upstream from -88 and only the last "gtg" bases appear at the beginning of Fig. 1).

Thus, the cited art does not disclose all the elements of the present invention nor provide any suggestion to employ SEQ ID NOS: 37-40 in combination with an HCV sequence of SEQ ID NOS: 1-15 on a solid substrate that permits simultaneous detection of HCV sequences and MBL polymorphism sequences. Furthermore, the prior art does not provide a reasonable expectation of success for the superior, synergistic results obtained by simultaneous detection of polynucleotide sequences from a pathogen (e.g., HCV) and a subject's gene polymorphism. Accordingly, this rejection would not apply to the new claims.

Rejection—35 U.S.C. §103

Claims 18, 19, 21, 22, 24, 32 and 33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Maertens et al., U.S. Patent No. 5,864,704, in view of Matsushita et al., J. Hepatol., 1998. This rejection is moot in view of the cancellation of these claims. It would not apply to the present claims for the following reasons.

Maertens has been address above and does not disclose the second probe sequences of SEQ ID NOS: 37-40.

Matsushita et al. do not disclose a method of using the sequences of SEQ ID NO: 37-40. Fig. 1 on page 696 refers to polymorphisms at -550, -221 and +4, but does not disclose the base sequence of the polymorphism encompassed by SEQ ID NOS: 37-40. The cited prior art does not disclose all the elements of the present invention, nor suggest the combination of an HCV probe comprising SEQ ID NOS: 1-15 and a second probe (MBL polymorphism) of SEQ ID NOS: 37-40, therefore this rejection would not apply to the new claims.

Rejection—35 U.S.C. §103

Claims 18, 19, 20, 22, 23, 24, 25, 32 and 33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Maertens et al., U.S. Patent No. 5,864,704, in view of Hijikata et al., Intervirology, 2001. This rejection is moot in view of the cancellation of these claims and would not apply to the present claims for the following reasons.

As discussed above, Maertens does not disclose the required MBL polymorphism sequences nor provide any suggestion for combination of an HCV sequence of SEQ ID NO: 1-15 with an MBL polymorphism sequence of SEQ ID NO: 37-40.

Hijikata, Fig. 1, discloses a polymorphism comprising a base sequence similar to that of SEQ ID NO: 39-40, see comparison table below:

Fig. 1		ctg	c/a	ag	gtg
SEQ ID NO: 37	g	ctg	**t**	ag	gtg
SEQ ID NO: 38	g	ctg	**g**	ag	gtg
SEQ ID NO: 39	g	ctg	**a**	ag	gtg
SEQ ID NO: 40	g	ctg	**c**	ag	gtg

Hijikata does not disclose the sequences of SEQ ID NO: 37 and 38 and therefore the invention as directed to these two sequences is not suggested by the cited prior art.

With respect to SEQ ID NOS: 39 and 40 (as well as 37 and 38), Hijikata does not suggest employing any of these sequences in combination with the HCV probes of SEQ ID NOS: 1-15. Accordingly, this rejection would not apply to the present claims.

Rejection--Double Patenting

Claims 18, 19, 20, 22, 23, 24, 25, 32 and 33 were rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-9 of

Hijikata et al., U.S. Patent No. 6,783,935, in view of Maertens, U.S. Patent No. 5,864,704. This rejection would not apply to the new claims which are directed to a substrate comprising a first probe of SEQ ID NOS: 1-15 and a second probe comprising SEQ ID NOS: 37-40.

The Hijikata claims are not directed to solid substrates comprising the probes required by the present invention and Maertens does not disclose or suggest such a solid probe either. In the event that this rejection is maintained, the Applicants respectfully request that this rejection be held in abeyance pending the identification of otherwise allowable subject matter, at which time it may be addressed by filing a terminal disclaimer, if necessary.

Provisional Rejection--Double Patenting

Claims 18, 19, 20, 22, 23, 24, 25, 32 and 33 were rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-8 and 25-28 of U.S. Application No. 10/633,659, in view of Maertens, U.S. Patent No. 5,864,704. The Applicants respectfully request that this provisional rejection be held in abeyance pending the identification of otherwise allowable subject matter, at which time it may be addressed by filing a terminal disclaimer, if necessary.

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. An early indication of such is earnestly requested.

Respectfully submitted,

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